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ARTICLE NEWS

# Florida Grand Jury Probing COVID Vaccine Issues Asks for an Extension + More

*The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that offers human health and the environment.*

By The Defender Staff

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## Florida Grand Jury Probing COVID Vaccine Issues Asks for an Extension

**Health News Florida reported:**

A statewide grand jury probing issues related to COVID-19 vaccines has asked the Florida Supreme Court to extend its term for six months. Gov. Ron DeSantis recently requested the Supreme Court extend the grand jury's term, which was originally set to expire on Dec. 26 in Hillsborough County for a year, according to a petition filed by Attorney General Ashley Moody.

The grand jury issued an interim report on Feb. 2 and is seeking an extension through Dec. 26.

"The statewide grand jury has diligently conducted its investigation regarding the issues identified by this honorable court's Supreme Court's order, several of which have required investigation outside of the state," the petition, filed by statewide prosecutor Nicholas Cox's office, said.

"Despite its diligent efforts, including the issuance of an interim report, the statewide grand jury has not completed its investigation at this time. A significant amount of work remains that may not be completed before the expiration of the term."

## Spending on Diabetes, Weight Loss TV Spots Climbs as Drugmakers Wrestle for Share

**Fierce Pharma reported:**

Drugmakers are bringing the fight for diabetes and weight loss spaces to the airwaves, with MediaRadar finding six leading brands ramped up TV spending by 46% over the first nine months of the year.

MediaRadar analyzed a sampling of ad spending from national TV broadcasters, publications and digital channels to understand who is spending what. The analysis identified six brands that powered spending on diabetes and weight loss ads past $1 billion last year. The drugs were Jardiance, Wegovy, Mounjaro, Ozempic, Farxiga and Rybelsus, several of which featured Serena Williams in 10 of the ads in the period.

The MediaRadar analysis looked at how spending changed over the first two months of the year. With Novo Nordisk resuming promotion, MediaRadar estimated that spending on Wegovy jumped by 125% in the first two months of 2024. Spending on Eli Lilly's Mounjaro skyrocketed by an estimated 111%.

Most of the ad dollars are going into television. MediaRadar found five of the top six diabetes and weight loss brands allocated at least 88% of their ad budgets to TV, causing their spending to ramp on to climb 46% over the first two months of the year.

## Asking Patients About Flu Shots in the Emergency Room May Boost Uptake

**CIDRAP reported:**

Simply asking patients to get the flu vaccine during emergency department (ED) visits may double vaccination rates — or raise the number by a third if the request is combined with helpful video and print messages, according to a study this week in NEJM Evidence.

The study, led by researchers at the University of California-San Francisco (UCSF), compared two interventions among 767 non-critically ill adult patients seen in the ED who were not yet vaccinated against influenza. The study was conducted in San Francisco, Houston, Philadelphia, Seattle, and Durham, North Carolina, during a single flu season, from October 2022 to February 2023.

Flu vaccine uptake was measured among those given no intervention, those given no messaging about flu shots but were asked about intentions to get vaccinated, and those given an influenza vaccine messaging platform consisting of a video, 1-page flyer, and scripted message of, "Would you be willing to accept the influenza vaccine?"

Thirty days after their ED visit, participants were asked if they had received a flu vaccine. Among those with no intervention, 15% had gotten vaccinated. Thirty-two percent of those who were asked about the flu vaccine intentions were vaccinated, and 41% of those who watched a video, got the flyer and were asked about their intentions had received a vaccine.

"The fact that simply mentioning vaccination had such a positive impact on future vaccination rates among our sample is incredible, and makes a strong case for incorporating vaccine messaging into emergency department workflows," said coauthor Efrat Kaen, MD, an emergency medicine physician from Thomas Jefferson University, in a press release from that school.

## Moderna Reports Promising Findings for Next-Generation COVID Vaccine

**CIDRAP reported:**

Moderna today announced promising interim phase 3 clinical trial findings for its next-generation COVID vaccine, which offers the potential for longer shelf life and paves the way for a combination mRNA vaccine against flu and COVID.

The mRNA-1283 vaccine showed a higher immune response — including in seniors — than its currently licensed vaccine, called mRNA-1273.222. The response was higher against Omicron BA.4/BA.5 as well as the original SARS-CoV-2 virus.

The trials enrolled more than 12,000 people ages 12 and older in the United States, Canada, and the United Kingdom. Researchers also found that mRNA-1283 had a similar safety profile as Moderna's currently licensed vaccine.

In a separate statement on the vaccine's potential contribution, Moderna said clinical trials of its combination flu-COVID vaccine (mRNA-1083) in people age 50 and older is fully enrolled and that it expects data this year. The U.S. Food and Drug Administration has granted it fast-track designation.

## AstraZeneca Claims Australian Rules Stopped It Defending Its Vaccine During Pandemic

**The Guardian reported:**

AstraZeneca has called on reforms to Australia's rules around discussion of medicines, saying public confusion over its COVID vaccine was created by a system that was restricted in explaining health warnings by the nation's medicines regulator. State governments in New South Wales, Western Australia and South Australia have also been critical of the federal response to the pandemic, raising concerns about the former Coalition government's decision-making, access to crucial data and poor coordination across jurisdictions.

One of the major disruptions to the nation's response in 2021 was the Australian Technical Advisory Group on Immunisation (Atagi) ruling that, due to "rare but serious" blood clots, the AstraZeneca vaccine should not be the preferred COVID jab for people under 50.

That vaccine, manufactured domestically, was envisaged as Australia's vaccine rollout "workhorse," with most people expected to receive that jab. But the April 2021 announcement, which was met with widespread confusion, said Pfizer — which Australia only had in short supply at the time — should be given to under-50s.

"The rollout of the COVID-19 vaccine AstraZeneca was impacted by public misperception relating to the risks associated with the vaccine. In preventing pharmaceutical companies from promoting medicines, [Therapeutic Goods Administration] regulations inadvertently prevented AstraZeneca from proactively presenting information to address concerns with adverse events," the company wrote in its submission.

## Mpox Cases in the U.S. Are on the Rise as Vaccination Rates Lag and New Threats Loom

**CNN Health reported:**

Mpox cases in the United States are twice as high as they were at this time last year, and experts are stressing the importance of improving vaccination coverage as transmission risks rise.

Transmission rates are still far below levels from 2022 when there were tens of thousands of cases in the U.S. But after a quieter year last year, experts say the U.S. is vulnerable to increases in cases in a number of ways. The public health emergency in the U.S. expired more than a year ago, cutting the amount of federal resources available to manage the public health response. And relatively low vaccination rates leave many at risk.

In December, the CDC also sent a health alert warning healthcare providers about another subtype of the virus that has been found to be more transmissible and cause more severe disease than the subtype associated with the 2022 outbreak in the U.S. This particular genetic clade has not been identified in the U.S., but it is spreading in the Democratic Republic of Congo.

The federal government managed the supply of mpox vaccines available in the U.S. during the public health emergency, but that process has since been commercialized. The government does have some supply remaining, and the vaccine is also expected to be available to private insurers and healthcare offices next month, experts say.

## Gardasil Lawsuits Over Failure to Warn Doctors About HPV Vaccine Risks Cleared to Move Forward

**AboutLawsuits.com reported:**

The U.S. District Judge presiding over all federal Gardasil lawsuits is allowing the litigation to move forward, after narrowing down plaintiffs' claims to whether Merck fraudulently concealed the HPV vaccine risks from doctors, or failed to adequately warn them about potential side effects users may experience.

There are currently about 200 product liability lawsuits filed against Merck & Co. in the federal court system, each involving similar allegations that the drug maker failed to disclose potentially serious health risks from the Gardasil vaccine, which has been widely administered to teens and young adults in recent years, to protect against the development of HPV infections and cervical cancer.

Although Merck has promoted the vaccine as safe and effective, lawsuits claim the company withheld critical information from both users and the medical community about severe and debilitating autoimmune complications, including postural orthostatic tachycardia syndrome (POTS), neurological problems, premature ovarian failure and other side effects.

## The Economics of Antibiotics Are Broken and Superbugs Are on the Rise — but a Solution Inspired by the Subscription Economy Could Save Millions of Lives

**Fortune reported:**

One day, you're fine. But then you get a cut or bruise, or undergo a common medical procedure, maybe a root canal or surgery for a torn ligament. You develop an infection — and everything changes. Try though they might, the doctors can't get it under control. They've run out of antibiotic after antibiotic, leaving in combination — until they simply run out of options. When that moment arrives, it can be a death sentence.

In the medical world, this is known as antimicrobial resistance. Today, many people succumb to the planet's public health threat as the viruses, bacteria, parasites, and fungi have evolved to resist our available varieties of antimicrobial drugs. We need urgent congressional action to address this nationwide problem.

Our country's pharmaceutical pipeline for antimicrobials is a classic case of market failure in urgent need of government correction. As currently configured, the incentive structure for new drug development doesn't work for antimicrobials as it does for other drugs.

As of this writing, there are only 50 antibiotics in clinical development. Of these, most will never see the light of day, either because the drugs won't make it through trials or the small companies that develop them will run out of funds.

Most of the large pharmaceutical manufacturers have quit the antibiotics business altogether, and it's easy to see why. By some estimates, it costs $1.5–$2.5 billion to develop an antibiotic, but annual sales average around $46 million. That's because doctors must prescribe new antibiotics as sparingly as possible to slow the spread of superbugs. The low sales volume makes for prohibitive financial math. Our supply can't keep up with demand.

## 'People Assume You're Crazy for Doing It': The Melbourne Clinic Infecting Healthy Patients

**The Guardian reported:**

Green plants, cool tones, casually placed scatter cushions: this living room in East Melbourne could belong to — or at least, be rented by — any millennial. The squeaky corridor floors are a giveaway, though; along with the beds on wheels.

This isn't a real estate opportunity, but Doherty Clinical Trials (DCT) — Australia's first unit dedicated to human challenge studies, where trial participants are given a dose of an infectious disease in a controlled setting. An offshoot of the Peter Doherty Institute for Infection and Immunity at the University of Melbourne, it opens on Monday — a breeding ground, its proponents hope, for discoveries that may redefine the future of the disease.

Human challenge trials, or controlled human infection model (CHIm) studies, are "highly valued as one of the most efficient ways to evaluate the efficacy of novel vaccines and therapeutics", Andrew Brockway, the facility's CEO, says. They serve two primary purposes: providing insight into diseases, such as flu or malaria, or "to more quickly determine if and how well a specific vaccine or drug in development works" by administering it to a vaccinated cohort, all of whom are subject to the same conditions.

Challenge trials, which began more than a century ago and have been spearheaded by the UK, Australia, Europe and the U.S., are costly to carry out and recruiting healthy volunteers can be difficult.

That has done little to dim the aspirations of DCT, which plans to move to a larger site in 2027. On the ground floor, a clinic area where participants will be infected with influenza, malaria, strep A and oral gonorrhea. Other trials, run in collaboration with industry partners and biotech companies, will test novel technologies, including a microneedle patch and a prophylactic nasal spray for COVID — both of which are designed to replace jabs altogether — while a Moderna tie-up will seek to develop mRNA vaccines. Brockway hopes the facility will become a "potentially contribute to the management of future pandemics" too.

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